ARAVA

(leflunomide)

Specific Patient Information

This information sheet has been developed in accordance with the current leflunomide package leaflet and should be read in addition to this package leaflet inserted in the medication packaging.

What should you know if you are a woman of childbearing potential, a woman planning to become pregnant or a man planning to father a child.

If you are a woman of childbearing potential or a woman planning to become pregnant

- **Leflunomide may increase the risk of serious birth defects**

You may be at increased risk of having a baby with a birth defect if:

- You are pregnant when you start taking leflunomide or
- You become pregnant while you are taking leflunomide or
- You do not wait to become pregnant until you have stopped taking leflunomide and followed the drug wash-out procedure described below, or
- You become pregnant within 2-years after you stopped leflunomide

- **Precautions of use for leflunomide**

If you are a woman of childbearing potential, you and your partner should take every precaution to avoid becoming pregnant, such as both partners using reliable birth control as recommended by your doctor when:

- You are currently taking leflunomide or
- You have discontinued leflunomide and are going through the drug wash-out procedure, or
- You have discontinued leflunomide less than 2-years ago

It is VERY IMPORTANT that you contact your doctor IMMEDIATELY if your menstrual period is at all late or if for any other reason you believe you may be pregnant.

- **Leflunomide wash-out procedure**

After discontinuing leflunomide, your doctor will order you a drug wash-out procedure.

The aim of this procedure is to remove the drug rapidly and sufficiently from your body. The wash-out procedure consists of a full 11-day course of certain drugs which speed up the removal of leflunomide from your body. This course is followed by 2 separate laboratory blood tests at least 14 days apart to assure a very low drug level in your body. If your leflunomide levels are still too high, a repeated drug wash-out procedure may be necessary.

When it is confirmed that leflunomide has been sufficiently removed from your body by the 2 separate laboratory blood tests, you should then wait for at least another month if you plan to become pregnant.

If you do not follow the drug wash-out procedure, it could take up to 2 years to reach this very low drug level in your blood.

If you are a man planning to father a child

As it can not be excluded that leflunomide passes into semen, reliable contraception during treatment with leflunomide should be guaranteed.

If you plan to father a child, you should discuss with your doctor who could advise you stop leflunomide and then undergo the drug wash-out procedure (as described above).

When it is confirmed that leflunomide has been sufficiently removed from your body, men should then wait for at least 3 months before attempting to father a child.

For further information, please contact your doctor.

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Call for Reporting

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

You can report side effects directly via HPRA Pharmacovigilance. Website **www.hpra.ie**.

Side effects should also be reported to Sanofi: Tel: **01 403 5600** e-mail to: **IEPharmacovigilance@sanofi.com**

This patient leaflet has been approved by the Health Products Regulatory Authority (HPRA).

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